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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,569	02/21/2002	Gholam-Reza Zadno-Azizi	38349-0102D	4156

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/081,569

Applicant(s)

ZADNO-AZIZI ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 January 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination

1. The request filed on 10/26/05 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on Application No. 10/081,569 is acceptable and a RCE has been established. An action on the RCE follows.

Response to Amendment

2. The amendment filed 10/26/05 has been entered. Claims 28-31 have been canceled. All pending claims 20-27 are being considered for further examination on the merits.

Terminal Disclaimer

3. The terminal disclaimer filed on 10/26/05 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent Nos. 5,954,766 and 6,632,243 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 20 and 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a device having a construction such that no air flow

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occurs across the valve, does not reasonably provide enablement for a device having a construction that completely blocks air flow through the bronchial passage. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. As cited by the applicant, page 4, lines 21-22 of the specification states that “the resilience of the body closes the slit 26 so that no flow can occur”. This provides support for claims 26 and 27, which require no air flow *across the valve*. There is no support, however, for the *device* in its entirety having a construction that completely blocks air flow through the bronchial passage. For example, the specification does not limit the inwardly extending disks 38 and 40 as completely blocking air if the device was implanted in a bronchial passage. The amended claim language of claims 20 and 23 discussed in the interview on 10/12/05 would only be permitted if fully supported by the specification. Because the limitation of “the device has a construction that completely blocks air flow” is not fully supported by the specification, the claims do not receive priority benefits of the parent applications. The effective filing date of claims 20-25 is February 21, 2002, which is the filing date of the application.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-25 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 23 recites the limitations "the device" and "the flow control device" in lines 7 and 10, respectively. There is insufficient antecedent basis for these limitations in the claim.

8. Claim 27 recites the limitations "the device" and "the flow control device" in lines 7 and 10, respectively. There is insufficient antecedent basis for these limitations in the claim.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alferness et al. (USPN 6,293,951, as cited in applicant's IDS) in view of Shaw (WO 01/87170 A1).

Alferness et al. discloses a pulmonic fluid-flow control device and system with all the elements of claims 20 and 23, but is silent to the valve being biased into the closed configuration. See Figure 11 for a pulmonic fluid-flow control device (110) including a one-way valve dimensioned for placement in a bronchial passageway (50), wherein the valve is moveable between an open configuration allowing air flow through the valve and a closed configuration restricting air flow through the valve (column 6, lines 47-50). See column 2, lines 28-41 and column 6, lines 51-55 for the device (110) having a construction that completely blocks air flow through the bronchial passageway when the valve is in the closed configuration. See Figure 11 and column 6, lines 16-29 for a frame (100) coupled to the valve, wherein the frame (100) self-expands within a bronchial passageway (50) sufficiently to anchor the flow control device (110)

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within the bronchial passageway (50). See Figure 6 and column 5, lines 29-32 for the one-way valve being so dimensioned as to be guidable into an outer sheath (70) for positioning the valve. Shaw discloses a bronchiopulmonary occlusion device (2) with a one-way flutter valve (5) that is biased to the closed position in order to prevent the ingress of respiratory gas. See Figures 1 and 2, page 4, lines 10-12 and page 5, line 9. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Shaw to modify the fluid-flow device of Alferness et al. by making the one-way valve biased in the closed position or replacing the one-way valve with a biased one-way flutter valve in order to prevent the ingress of respiratory gas.

With respect to claims 21 and 24, the fluid-flow control device (110) of Alferness et al., like the device of applicant, is sized for placement within a bronchial passageway. Therefore, the valve of device (110) will have an outer diameter of approximately 0.349 inches.

Claims 22 and 25, see Figure 11 and column 6, lines 44-45 for the valve including a valve body (94) having a slit (104) through which fluid can flow.

11. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andersen et al. (USPN 5,411,552, as cited in applicant's IDS) in view of Moasser (USPN 4,417,360).

Andersen et al. discloses a pulmonic fluid-flow control device and system with all the elements of claims 26 and 27, but is silent to the valve being biased into the closed configuration. See column 3, lines 44-45 and column 7, lines 12-14 for a fluid-flow control device (9) including a synthetic one-way valve (6) that is sized for placement within the pulmonary artery. Since the

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size of the human pulmonary artery ranges from about 5mm in an infant up to about 35mm in a full sized adult, as evidenced by Ruiz (USPN 5,868,779) and Ruiz (USPN 5,954,765) which were both cited in the office action mailed 4/27/04, the valve of Andersen et al. will be dimensioned for placement in a bronchial passageway. See Figure 2 and column 2, lines 35-36 for a frame (1) coupled to the valve (6) by gluing or welding. See column 2, lines 47-52, column 3, lines 44-45, column 4, lines 9-11, column 6, lines 30-33 and Figure 7 for the frame (1) self-expanding to anchor the flow-control device (9) within the pulmonic passageway (pulmonary artery). When placed within a bronchial passageway, the valve (6) would be movable between an open configuration allowing air flow through the valve and a closed configuration restricting air flow through the valve, and the frame (1) would self-expand sufficiently to anchor the device (9) within the bronchial passageway. See column 2, lines 45-52 for the one-way valve (6) being guidable in an elongate passage (protection cap 11A) for positioning the valve. See column 6, lines 30-36 and Figure 7 for the device being expanded to a diameter greater than the diameter of the body passageway into which it is implanted, thereby preventing fluid-flow between the outer surface of the device and the interior of the passageway at the points of contact to form a seal therebetween. Because the valve (6) is mounted to the frame (1) by gluing or welding, there are no holes formed in the valve. Therefore, when implanted into the bronchial passageway, the device (9) has a construction such that no air flow would occur across the valve (6) when the valve is in the closed configuration. Moasser teaches a prosthetic valve (10) with a closure assistance means (19) that includes a pair of flaps (18, 20) with magnetic member (28, 30) at the ends thereof to exert a mutually attractive force on one another to create a valve closing force. With this magnetic member arrangement, the valve (10) does not rely solely upon back pressure

to cause valve closure, but rather, is able to effect valve closure before the build-up of any significant back pressure which would tend to bring the valve flaps into violent contact. The soft, non-traumatic closing of the flaps assisted by the attractive forces exerted by the magnets in the distal ends of the flaps is quiet, avoids disturbance to the patient, and is smooth to eliminate the turbulence that can lead to subsequent hemolysis. See Figures 1 and 3. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to modify the valve of Andersen et al. by making the valve biased in the closed configuration using the arrangement of magnetic members taught by Moasser in order for the closing of the flaps of the valve (6) to be to soft, non-traumatic, quiet, not disturbing to the patient, and smooth to eliminate the turbulence that can lead to subsequent hemolysis. See column 3, lines 66-68, column 4, lines 20-24, column 5, lines 40-42 and column 6, lines 18-25.

Response to Arguments

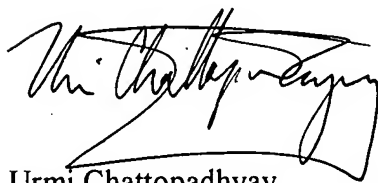
12. Applicant's arguments filed 10/26/05 have been fully considered but they are not persuasive. Applicant argues that the Andersen valve has a construction that would not completely block air flow when the valve is closed because the valve is attached to the stent by suturing, thereby creating suture holes that form leak paths for air to pass across the valve even when the valve is closed. The examiner would like to point out column 2, lines 35-37 of Andersen et al., which discloses mounting the valve to the stent by gluing or welding, as an alternative to suturing. When mounting by gluing or welding, no suture holes will be created in the valve. Therefore, the device will indeed have a construction such that no air flow occurs *across the valve* when the valve is in the closed configuration.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached Monday through Thursday and every other Friday from 9:00am to 6:30pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay

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David J. Isabella
Primary Examiner